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To: secretariat@srcr-scrr.gc.ca

RE: TCPS 2 CONSULTATION

Dear Secretariat.

Thank you for the opportunity to comment on the proposed revised guidance's to the TCPS 2 2018. The below commentary is focussed primarily upon the Proposed Guidance Regarding Broad Consent for the Storage and Use of Data and Human Biological Materials. I have made very brief references to the other proposed revised guidance's at the end of this submission.

I am commenting personally, from the Province of BC, in my capacity as Director, University of British Columbia Office of Research Ethics. My main discipline is research ethics which is an area that I have been working in for almost 20 years.

Because the proposed revisions generally reflect UBC's current guidelines on databases and biobanks, I was initially not going to comment. Obtaining broad consent for future unspecified use of human data and biological materials in research has been permissible at UBC (any many other Canadian Institutions) for a number of years. It was necessary for Research Ethics Boards to develop policies and guidelines pertaining to the creation of databases and biobanks, given that their creation for research purposes was becoming increasingly common and given that there were no obvious areas for their oversight aside from institutional Research Ethics Boards.

UBC's guidelines will require some minor revisions related to: requests by researchers who are not subject to the TCPS2 2018; seeking community consent; ongoing consent and ongoing consent where there is a change in capacity. I agree with the proposed revisions and thank the Panel for formalizing their guidance concerning this increasingly important area of research. The emphasis on good governance is particularly welcome.

There are only two areas within the guidance that I would like to comment upon specifically. The first is the provision at Lines 64 -68 and the potential need to consult with or seek permissions from specific or unique community groups. I agree wholeheartedly that this is an important requirement in such cases. I believe that the Panel may wish to consider adding to their guidance some commentary (not necessarily in this particular section) concerning the ethical use of disaggregated demographic data and the avoidance of harm to systemically oppressed communities if such data is misused. Consideration might be given to recognizing that de-identification of data is no longer the only protection that researchers should afford to special communities and that consideration also needs to be given to ensuring that vulnerable communities participate in and benefit from data collection that impacts them. Human rights law principles should apply to disaggregated demographic data, and researchers should be aware of both the benefits of respectfully used and collected disaggregated data as well as the risks of collection and disclosure of such data when systemic inequalities between diverse categories become visible.

The second comment that I would like to make is in relation to Lines 79 – 85. I would like to thank the Panel for pointing out that both specific and broad consent must be obtained when research is being conducted for a specific project, but also with the intention of subsequently storing those data or materials for subsequent unspecified research. Your points relating to the need to ensure that research is conducted in a manner that is free from coercion and/or undue influence are well taken. Articulation of the principal that participating in a specific and known project must not be contingent on the participant consenting to unspecified research is particularly welcome. Increasing pressure has been being put on Research Ethics Boards (and participants) to allow mandatory data collection and retention in the context of specific research projects. I recognize that there is some diversity of opinion concerning this particularly in relation to research that does not provide a direct benefit. In my opinion, even if there is no real possibility of direct benefit from the specific research, mandatory provision of personal data or biological materials to a repository for future use contravenes the fundamental principle of voluntary consent. I believe that there is a fundamental distinction between this principle and the requirements of the Tri-Councils under the FAIR guiding principles as well that of many research journal requiring that authors make their data available for replication and the avoidance of scientific fraud. In the former situation, the required contribution is to a researcher run and researcher governed repository that is not necessarily publicly accessible and that would presumably store data from multiple related studies. In the latter situation, only the data from the specific study must be provided, and it must be publicly accessible.

A recent example of this issue came before the UBC-affiliated Children & Women's Research Ethics Board, in research related to the safety and efficacy of COVID-19 vaccinations for children under 12. The sponsor has been refusing to make data and tissue banking optional.

My comments related to the proposed guidance related to multi-jurisdictional research are included in the Research Ethics BC / UBC affiliated REB's response.

I agree with the proposed changes related to stem cells, in particular the exemption from REB review for de-identified cell lines.

Once again, thank you for the opportunity to comment.

Laurel Evans

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